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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,913	07/14/2003	Edward Faeldt	9000/2022	7967
29933 7590 03/24/2008 Edwards Angell Palmer & Dodge LLP 111 HUNTINGTON AVENUE BOSTON, MA 02199				
EXAMINER ZHOU, SHUBO				
ART UNIT 1631		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/618,913

Applicant(s)

FAELDT ET AL.

Examiner

Shubo (Joe) Zhou

Art Unit

1631

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/2/08, 7/3/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8, 13, 14, 18-20, 27, 28 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-12, 15-17, 21-26, 29, 30, 32-35 and 37 is/are rejected.
- 7) ☒ Claim(s) 5 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 1/2/08 has been entered.

Applicant's arguments in response to the previous Office action mailed 1/5/07 have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections are either reiterated from the previous Office action or newly applied but necessitated by applicant's amendments, and constitute the complete set presently being applied to the instant application. Rejections and/or objections set forth in the previous Office action but not reiterated herein are hereby withdrawn.

Status of Claims

Claims 1-30 and 32-37 are pending, claims 7-8, 13-14, 18-20, 27-28, and 36 have been previously withdrawn from further consideration, and claims 1-6, 9-12, 15-17, 21-26, 29-30, 32-35, and 37 are presently are under examination.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-12, 15-17, 21-26, 29-30, 32-35, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2, as amended, recite the limitation "providing a population of transgenic insects comprising a human neurodegenerative disease gene." The metes and bounds of the limitation are not clear because it is unclear whether each member of the population comprises the human neurodegenerative disease gene or the population as a whole comprises the human neurodegenerative disease gene, i.e. some members may not comprise the human gene. As such, claims 1-6, 9-12, 15-17, 21-26, 29-30, 32-35, and 37 are indefinite.

Claims 1 and 2 recite "before the administration of a said test agent." The phrase "a said test agent" is confusing. It is not clear whether "said test agent" is meant, i.e. the agent recited in the preamble whose effect on a population of insect is to be tested, or "a test agent" is intended, i.e. could be any test agent. As such, the phrase "said test agent" in the "administering" step lacks clear antecedent basis because it is unclear whether it means the test agent recited in the preamble or the any test agent recited in the "identifying" step.

Claim 1 recites identifying a trait of a specimen in the population before the administration of a test agent and "creating a digital image showing a trait of specimens in the population" and compare the trait before and the trait after. The metes and bounds of the

invention are not clear because it is unclear whether the two traits are the same trait or same type of trait, i.e. eye color, etc. If it is not the same trait, it is unclear how two different types of traits, e.g. eye color versus shape of wing, could be compared. If it is the same trait, it is suggested that "the" or "said" in lieu of "a" be used before "trait" in the "creating" step.

Claim 5 recites "[t]he method of claim 1 or 2 wherein said trait is" The phrase "said trait" lacks clear antecedent basis because there are multiple traits recited in claim 2, i.e. "at least two traits," and thus it is not clear which one is meant by "said trait" in claim 5.

Similarly, the phrase "said trait" recited in claim 9, line 5, lacks clear antecedent basis for the same reason as that set forth above for claim 5.

The phrase "said at least one trait" recited in claim 9, lines 7-8, lacks sufficient antecedent basis because there is prior reference to "at least one trait."

The phrase "more or less similar" recited in claims 10 and 15 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. With a clear standard set forth, one skilled in the art would not know whether or not a particular agent phenoprofile is more or less similar to the reference phenoprofile. This rejection is reiterated from the previous Office action with modification. Applicant argues that "the claims are not indefinite because, upon reading the claims in view of the specification, one of skill in the art would be appraised of the boundaries of what constitutes infringement of the claim." See page 13 of the response. This is not found persuasive because as set forth above, without a clear standard or criterion to define "more or

less similar,” one skilled in the art would not know the boundaries of the phrase. For instance, if a particular agent phenoprofile shares 30% similarity with the reference phenoprofile, one skilled in the art would not know whether this falls within the boundary of being “more or less similar.”

The phrase “said step of determining” recited in claims 12 and 21 lacks sufficient antecedent basis because claim 9 does not recite a step of “determining.”

The phrase “said at least two traits” recited in claim 22 lacks sufficient antecedent basis because claim 21 or claim 1 or 9 does not recite “at least two traits” but “more than one trait” in claim 21, “a trait” in claim 1, and “at least one trait” in claim 9.

Claim 37 recites steps of “providing,” “administering,” “creating,” “generating” and “identifying.” The relationship of the step “creating” with other steps such as the “generating” step is not clear because the result of the “creating” step is not used in the “generating” step.

Clarification of the metes and bounds of the claims is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 9-12, 15-17, 21-26, 29-30, 32-35, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Botas, US 2004/0177388.

This rejection is reiterated from the previous Office action.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Botas discloses a method for screening for a compound having activity against neurodegenerative disorder in transgenic insects (*e.g.*, *Drosophila*) comprising providing a population of transgenic insects having a human neurodegenerative disease gene (claims 48-57), administering an agent, creating a digital image showing a trait in a population ([0299]-[0303]), and correlating the trait with the effect ([0288]-[292]). Thus, Botas anticipates claims 1-2. Botas discloses quantifying a trait ([0300], claim 48), thereby anticipating claims 3-4. Botas discloses modifying and quantifying a climbing behavior [0300]-[0301], thereby anticipating claims 5-6. Botas discloses an agent screening assay using various compounds and a test and reference fly populations and ranking agents according to their activity (claims 48-52, [0300]-[0318]), thereby anticipating claim 9. Botas discloses determining an agent and reference phenoprofile (*i. e.*, a trait and a quantitative characteristic of the trait), comparing both phenoprofiles, and selecting and agent (claims 48-52, [0300]-[0301]), thereby anticipating claims 10-12, 15-17, and 21-23. Botas discloses an insect phenotype with characteristics of a mammalian disease (claim 56),

thereby anticipating claims 24-26, 29-30, 33, 35, and 37. Botas discloses transgenes for gene encoding a polypeptide with an expanded polyglutamine tract [0007], thereby anticipating claim 32. Botas discloses mutation which results in loss or gain of a function ([0007]-[0011]; claims 48-58], thereby anticipating claim 34.

Applicant's argument filed 7/3/07 with regard to this rejection has been fully considered but it is not found persuasive. Applicant argues that Botas does not disclose creating a digital image showing a trait in the population. This is not found persuasive because Botas discloses multiple digital images including those in Figs 1A through 1G, 2A through 2G, 6A through 6K, and especially 7A through 7A, showing multiple traits from population of the transgenic fruit flies.

Double Patenting

Claims 1-6, 9-12, 15-17, 21-24, 25-26, 32-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-12, 15-17, 21-24, 25-26, 29, 30-33 of copending Application 10/676,424 ("App. '424"). A group of claims (29 and 30) is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of App. '424.

Claim 30 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of copending Application 10/676,424 ("App. '424"), in view of Botas, US 2004/0177388.

These rejections are reiterated from the previous Office actions.

In the response filed 7/3/07, applicant did not provide arguments with regard to the double patenting rejections.

In previous responses, Applicants indicated that they would file a terminal disclaimer upon the notification of allowable subject matter in the instant claims. Applicant is advised that until a terminal disclaimer is filed or claims of the copending and/or the instant application are amended so that the claimed subject matter of the copending and the instant applications is patentably distinct, the rejection under the judicially created doctrine of double patenting will be maintained and no allowable subject matter will be indicated. A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

For the reasons stated above and in the previous office action, the rejection is maintained.

Claim Objections

Claims 5 and 33 are objected to because of the following reasons including informalities:

There is a half parenthesis ")" after the word "unit" in claim 5, which is confusing.

Claim 33 recites "wherein the expression of the transgene results neurodegeneration in said specimen." It seems that the word "in" is missing after the word "results."

Appropriate correction is required.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER